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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,349	09/12/2005	Atsushi Nagasawa	0230-0219PUS1	5681

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EXAMINER
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BADR, HAMID R

ART UNIT	PAPER NUMBER
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1794

NOTIFICATION DATE	DELIVERY MODE
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09/08/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/520,349	<b>Applicant(s)</b> NAGASAWA, ATSUSHI	
	<b>Examiner</b> HAMID R. BADR	<b>Art Unit</b> 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 16-25,27,29,31 and 32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 16-25,27,29,31 and 32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

**Applicants' amendment file on 5/09/2008 is acknowledged.**

**Claims 16-25, 27, 29, 31-32 are being considered on the merits.**

1. Upon reconsideration of Nakagawa et al. (1994, Construction from a single parent of baker's yeast strains with high freeze tolerance and fermentative activity in both lean and sweet doughs; hereinafter R1) and in light of the new grounds set forth below with respect to 35 U.S.C. 112, the indicated allowability of claims 17-25, 27, 29, and 31-32 is withdrawn. A rejection based on Nakagawa et al. (1994) is set forth below.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 20, 23-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Since the microorganism(s) is/are essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism(s) is/are not so obtainable or available, the requirements of 35 USC 112 may be satisfied by deposit(s) of the

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microorganism(s). The specification does not disclose a repeatable process to obtain the microorganism(s) and it is not clear from the specification or record that the microorganism(s) is/are readily available to the public.

This rejection may be overcome by establishing that the each microorganism identified is readily available to the public and will continue to be so for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer, or by an acceptable deposit as set forth herein.

If the depository is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his/her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney over his/her registration number, showing that,

- (a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon the granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and,

(d) the deposit will be replaced if it should ever become inviable.

The specification must also state the date of deposit(s), the number(s) granted the deposit(s) by the depository and the name and address of the depository.

3. Claim 16-19, 21-22, 31-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The word “expand” is not supported by the specification.

4. Claims 16-19, 21-22, 25, 27, 29, 31-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a specific strain, does not reasonably provide enablement for any strain of baker’s yeast. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Case law holds that applicant’s specification must be “commensurately enabling [regarding the scope of the claims]” *Ex Parte Kung*, 17 USPQ2d 1545, 1547 (Bd. Pat. App. Inter. 1990). Otherwise undue experimentation would be involved in determining

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how to practice and use applicant's invention. The test for undue experimentation as to whether or not all compounds within the scope of claims 16-19, 21-22, 25, 27, 29, 31-32 can be used as claimed and whether claims 16-19, 21-22, 25, 27, 29, 31-32 meet the test is stated in *Ex parte Forman*, 230 USPQ 546, 547 (Bd. Pat. App. Inter. 1986) and *In re Wands*, 8 USPQ2d 1400, 1404 (Fed.Cir. 1988). Upon applying this test to claims 16-19, 21-22, 25, 27, 29, 31-32, it is believed that undue experimentation would be required because:

5. Level of skill in the art: Different strains have different biochemical properties.

What holds true for one species does not need to hold true for other ones.

6. The presence of Examples: The example provided by the applicant has a limited showing with respect to other strains of baker's yeast.

7. Level of Unpredictability: A limited showing with respect to a specific strain does not translate to all strains of baker's yeast. There is no way to predict how other species will behave. There is no way to predict the isobutyric content of other species.

8. In light of the above factors, it is seen that undue experimentation would be necessary to make and use the invention of claims 16-19, 21-22, 25, 27, 29, 31-32.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 16-19, 21-22, 24-25, 27, 29, 31-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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11. Claims 16, 22, 24-25, 27, 29, and 32 are indefinite for “a weak offensive taste and odor characteristic of yeast”. It is unclear what is meant by “a weak”. It is not clear what the applicant regards as the invention. It is not clear what is meant by “offensive taste and odor”. These terms are subjective terms and “offensive” to one individual is not necessarily offensive to another. It is not clear what the applicant regards as the invention. It is unclear what is meant by “characteristic”. It is not clear what the applicant regards as the invention.

***Claim Rejections - 35 USC § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 16-19, 21-22, 25, 27, 29, 31-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakagawa et al. (1994, Construction from a single parent of baker's yeast strains with high freeze tolerance and fermentative activity in both lean and sweet doughs; hereinafter R1).

14. R1 studies the hybridization of spores of *Saccharomyces cerevisiae* (commercial baker's yeast) to construct a baker's yeast which is freeze-tolerant and has fermentative activity in both lean and sweet doughs (Abstract).

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15. R1 teaches determining the mating types to be used for their hybridization process (Page 3500, Col. 1, Determination of mating type).

16. R1 discloses the process of construction of hybrids. The isolated haploid strains showing opposite mating types are crossed by mixing in liquid medium. After the hybridization process, isolated strains are checked for their sporulation ability. Spore forming isolates are considered hybrids. (Page 3500, Col. 1, construction of hybrids)

17. R1 gives details of dough ingredients for lean, regular and sweet doughs. A commercial hard wheat flour is used having 12% protein and 0.36% ash (Page 3500, Col. 1 ingredients of doughs and Table 1).

18. R1 teaches the dough raising test by measuring the carbon dioxide evolved after 2 hours at 30°C. (Page 3500, Col.1 dough raising test)

19. R1 explains the frozen dough system where the prepared doughs are stored at -20°C for 1 week. After the freezing period, the thawed dough is placed in a bottle of Fermograph and the dough raising activity is measured for 2 hours. (Page 3500, Col. 1 Frozen dough system)

20. R1 indicates that it is possible to obtain strains with more improved qualities such as leavening ability and freeze tolerance than the commercial baker's yeast now available. (Page 3502, Col. 1, lines 13-17)

21. Low concentration of isobutyric acid is inherent in the *Saccharomyces cerevisiae* baker's yeast because all varieties of bread prepared with this yeast have fresh baked aroma and flavor and there is no bread known to have bad taste or aroma. On the other hand the instant specification states that "Although substances responsible for the



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offensive taste and odor characteristic of yeast are composed of a wide variety of compounds and are difficult to restrict to one kind of compound, it is estimated that isobutyric acid which is known as a linear fatty acid having a foul odor **may** be one of the causative substances.” (page 8, lines 14-19). Therefore, the role of isobutyric acid is not pivotal for the limitation of claim 16.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-T 5:00 to 3:30 (Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Callie Shosho can be reached on (571) 272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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